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Fuji Chemical Industries USA, Inc.

Fuji Spray Drying Newsletter

Vol 5: Analytical Expertise

Innovation for small-molecule compounds

Analytical Support

Fuji Chemical Industries has excellent analytical support for the development and manufacturing of the spray dried dispersion materials.

1 ICH Stability studies

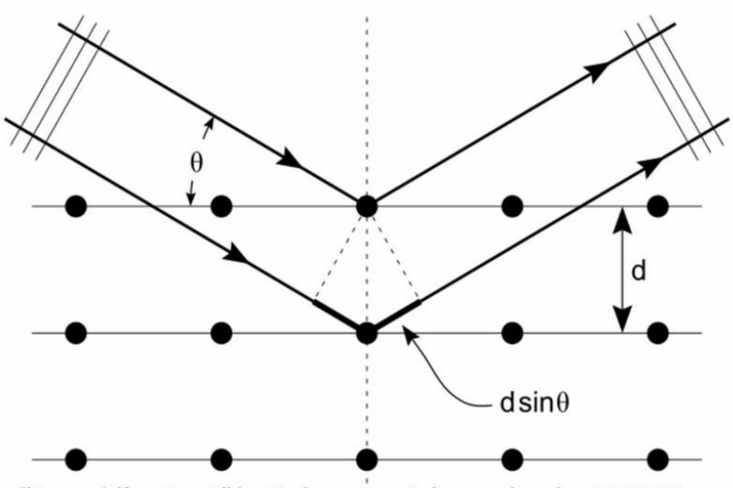
- **25℃ ± 2℃ / 60% RH ± 5%**
- **30℃ ± 2℃ / 65% RH ± 5%**
- **40℃ ± 2℃ / 75% RH ± 5%**

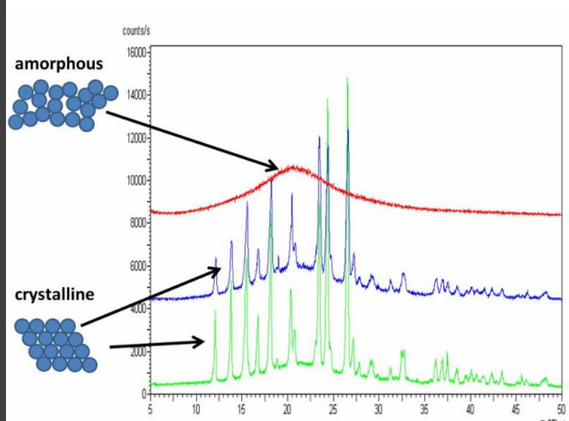
2 Full range of equipment for :
-Drug Substance and
-Drug Product

3 Analytical method development

4 Method validation

XRD Analysis

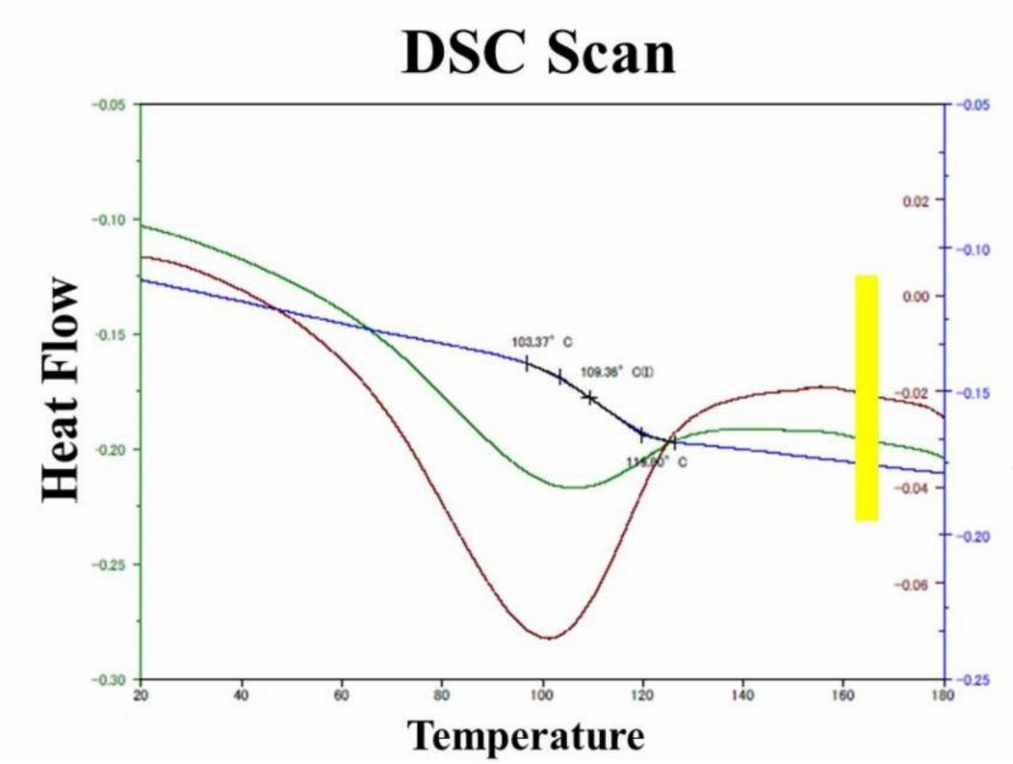




At Fuji, X-ray diffraction (XRD) is used to determine the degree of amorphism in the sprayed dried material. Focused beam of X-ray is directed at the sample material. Diffraction occurs when the X-ray beam is scattered by series of atoms arranged in long range order, causing "constructive interference" at specific angles.

Long range periodic pattern of the crystalline material will scatter the x-rays in only certain directions, causing sharp peaks in the XRD diffractogram. In contrast, amorphous materials lack the long range ordered pattern observed in the crystalline materials. This will result in scattered x-rays, causing broad halo pattern peak distributed over wide orientation range (2 theta) as opposed to sharp narrow peaks of its crystalline counterpart.

Differential Scanning Calorimetry



We also use DSC (Differential Scanning Calorimetry) to ascertain the appropriate characteristics such as the presence/absence of glass transition temperature, crystallization temperature, or melting temperature. Glass transition temperature indicates the degree of amorphism. Generally, higher glass transition temperature is indicative of higher stability of the material in maintaining amorphous state, and it is known that glass transition temperature decrease when phase separation and crystallization in a solid dispersion proceeds.

The temperature of the material is raised at a constant rate over the specified range. As the material is heated, any changes in the heat flow of the material from the state transition (e.g., glass transition, crystallization, or melting) are observed as peak or slope change. The DSC spectrum of the material is compared with that of the reference with specific peaks or change in slope which are appropriate for the material.

In this issue of our technical newsletter, we have shown you an outline of our technical service and GMP support. For more details, please contact our U.S. office office shown below:

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